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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,490	09/19/2003	Jian Li	CEN0312NP	8016
27777	7590	12/29/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			WOODWARD, CHERIE M.	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED  
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J&J PAT. DKT. SECTION



### Office Action Summary

**Application No.**

10/666,490

**Applicant(s)**

LI ET AL.

**Examiner**

Cherie M. Woodward

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7, drawn to a method for augmenting an immune response in a patient, classified in class 424, subclass 810.
  - II. Claims 8-11 drawn to a preparation of dendritic cells, classified in class 435, subclass 41.
  - III. Claim 12, drawn to a method of driving hematopoietic stem or progenitor cells to a dendritic cell lineage, classified in class 424, subclass 577.
  - IV. Claims 13-14, drawn to a method of preparing an antigen-presenting dendritic cell population, classified in class 435, subclass 41.
  - V. Claim 15, drawn to a method of preparing antigen-specific Tcells, classified in class 435, subclass 41.
  - VI. Claims 16-17, drawn to a process of preparing a matured dendritic cell, classified in class 435, subclass 41.
  - VII. Claim 18, drawn to a composition containing IL-18 matured DC, classified in class 435, subclass 41.
  - VIII. Claim 19, drawn to a method of administering a composition containing IL-18 matured DC, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II/IV, II/VI, II/VII, IV/VII, VI/VII, and VII/VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).
3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I, III, IV, VI, and VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires administration of a composition having at

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least one IL-18 biological activity, which is not required by any of the other groups. Invention III requires contacting hematopoietic stem or progenitor cells with flt3-ligand, which is not required by any of the other groups. Invention IV requires purification of antigen-expressing dendritic cells, which is not required by any of the other groups. Invention VI requires exposing dendritic cells to an antigen-specific peptide, which is not required by any of the other groups. Invention VIII requires the administration of a composition containing IL-18 matured DC cells into a patient intravenously, which is not required by any of the other groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

4. Inventions I, III, VI, and VIII are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

5. Inventions I/II, I/V, I/VII, II/III, II/V, II/VI, II/V, II/VIII, III/V, III/VII, IV/V, V/VI, V/VII, and V/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group I can be used with different molecules having at least one IL-18 biological activity. Group II requires administration to a patient with HIV. Group III requires IL-18 to be administered and can be used with different diseases. Group IV requires dendritic cells be exposed to an antigen-specific peptide. Group V requires T cells be exposed to antigen presenting dendritic cells. Group VI can be used in obtaining different biological fluids containing stem cells from a host. Group VII requires IL-18 matured DCs. Group VIII requires infusing a preparation of cells into a patient intravenously.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim

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will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in Light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CMW

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER

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# 2006

## GKT Current Docket

Due	Docket #	Serial #	Action	Comments
<b>JAN</b>				
1/27	CEN0312	10/666,490	RestReq - 1 Mo REPLY	
1/27	CEN0296	10/452,646	RestReq - 1 Mo REPLY	RELP MABS <b>ABANDON</b>
<b>FEB</b>				
2/7 1MX	CEN0243		Non-Compliant Amend 1 Mo REPLY	
2/9	CEN0250 NP	09/920,137	RestReq - 1 Mo REPLY	
2/9 2MX	CEN0290	10/393804	IDS, FF Ref cited	
2/11	CEN5029	10/867,992	RestReq - 1 Mo REPLY	
2/14 2MX	CEN5038	10/953,613	SeqListg VerStatmt	
<b>MAR</b>				
3/4 2MX	CEN5077		SqLg; Resp; DEC	1/19 Assign Filed; DEC awaiting SqLg
3/15 2MX	CEN5078		SqLg; DEC	1/19 Assign Filed; DEC awaiting SqLg
3/18 2MX	CEN5074		Sq Lg; DEC	1/19 MM Assign Filed; DEC awaiting SqLg
3/31	CEN5093		CONVERT to NP/PCT	
<b>APR</b>				
4/29	CEN0311 Indonesia		Request Xm	
<b>MAY</b>				
5/11	CEN5097		CONVERT to NP/PCT	
5/19	CEN5098		CONVERT to NP/PCT	
5/19	CEN5099		CONVERT to NP/PCT	
5/19	CEN5100		CONVERT to NP/PCT	
<b>JUN</b>				

<b>JUL</b>			
<b>AUG</b>			
8/30	CEN5109	CONVERT to NP/PCT	
<b>SEP</b>			
9/30	CEN5112	CONVERT to NP/PCT	
<b>OCT</b>			
<b>NOV</b>			
<b>DEC</b>			